Exhibit 30

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF
OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
This document relates to:	)	Case No. 17-md-2804
All Cases	)	Hon. Dan Aaron Polster

ALLERGAN'S AMENDED WRITTEN RESPONSES TO TOPICS 7, 20, 28, AND 41 IDENTIFIED IN PLAINTIFFS' AMENDED NOTICE OF DEPOSITION PURSUANT TO RULE 30(B)(6)

Allergan hereby provides the following amended responses and objections to Topics 7, 20, 28, and 41 of Plaintiffs' Amended Notice of Deposition Pursuant to Rule 30(b)(6). Allergan hereby incorporates all objections set forth in its August 24, 2018 Amended Responses and Objections to Plaintiffs' Amended Notice of Deposition Pursuant to Rule 30(b)(6) and Document Request Pursuant to Rule 30(b)(2) and Rule 34, its October 22, 2018 Second Amended Responses and Objections to Plaintiffs' Amended Notice of Deposition Pursuant to Rule 30(b)(6) and Document Request Pursuant to Rule 30(b)(2) and Rule 34, and its November 16, 2018 Second Amended Responses and Objections to Plaintiffs' Amended Notice of Deposition Pursuant to Rule 30(b)(6) and Document Request Pursuant to Rule 30(b)(2) and Rule 34 to the extent not overruled by the court or separately agreed-to.

Affirmation That Discovery Responses Herein Are Submitted On Behalf of All Current Allergan Entities And Include Information Collected About Prior Affiliates No Longer Owned by Allergan

These responses are made on behalf of Allergan Finance, LLC and Allergan plc -- a foreign corporation which has not been served (collectively Allergan).[1] Allergan confirms that it's previous and ongoing discovery investigation and production of documents -- regarding Kadian®, Norco®, and generic opioids manufactured and/or sold by the Actavis Generics Entities sold to Teva (and where appropriate, "opioids generally" or unbranded marketing) -- has included all responsive documents and information reasonably accessible to all of its current affiliates, including Allergan plc.

WRITTEN RESPONSES TO DEPOSITION TOPICS

TOPIC NO. 7: The identity of all Persons who were responsible for testing the safety and efficacy of Opioid Products for long-term use or for chronic pain, or who received reports, test results, studies or any other documentation regarding the testing of the safety and efficacy of Opioid Products for long-term use or for chronic pain.

JULY 11, 2018 RESPONSE TO TOPIC NO. 7: Allergan Finance incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. Allergan Finance objects to this Request to the extent it seeks information more appropriately sought through written interrogatories, document requests, or other forms of discovery that are less burdensome and more appropriate vehicles for the information sought.

[1] In an order entered November 9, the Court lifted the stay on service of foreign entities, noting at a telephonic hearing that foreign parents including Allergan plc were deemed to be parties in the case. Allergan plc objects to the lack of due process and to the Court's refusal to allow briefing contesting personal jurisdiction on behalf of a foreign entity not subject to jurisdiction in this Court.

Subject to and without waiving its objections, Allergan Finance will designate a witness to testify regarding the identity of the primary individuals involved with efforts regarding the safety and efficacy of branded Schedule II opioids since Allergan Finance owned these opioids. For clarity, Allergan Finance does not agree to provide information about testing regarding safety or efficacy that were completed prior to the date Allergan Finance's predecessors acquired Kadian®, and does not agree to provide information about testing regarding safety or efficacy of branded versions of generic opioids owned by Allergan Finance's predecessors.

AUGUST 24, 2018 AMENDED RESPONSE TO TOPIC NO. 7: Allergan incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. Allergan objects to this Request to the extent it seeks information more appropriately sought through written interrogatories, document requests, or other forms of discovery that are less burdensome and more appropriate vehicles for the information sought.

Subject to and without waiving its objections, Allergan will provide a written response identifying the primary individuals involved with efforts regarding the safety and efficacy of Kadian® and Norco® since Allergan owned these opioids. For clarity, Allergan does not agree to provide information about testing regarding safety or efficacy that were completed prior to the date Allergan's predecessors acquired Kadian®, and does not agree to provide information about testing regarding safety or efficacy of branded versions of generic opioids owned by Allergan's predecessors.

JANUARY 15, 2019 WRITTEN RESPONSE TO TOPIC NO. 7: Subject to and without waiving its objections, Allergan refers Plaintiffs to its response to Topic No. 20. Further, the following were among the individuals involved with efforts regarding the safety and efficacy of Kadian®, Norco® and generic opioids:

- **Primary individuals involved with the FDA-approved Risk Evaluation and Mitigation Strategies ("REMS"):** Terri Nataline; Janet Pientka; Monique Weitz; Gary Kozloski; Joann Stavole; Madlen Michael; Burke Byrne; Charlene Salmorin; Carla Hedrick; and Charles Ebert.

- **Primary individuals involved with opioid Post-Marketing Requirements:** Pamela Matheny and Nicola Walters.

- **Primary individuals involved with adverse event reporting and other pharmacovigilance activities:** Joe Viscosi; Sarita Thapar; Madlen Michael; Jasmine Shah; and Terri Nataline.

- **Primary individuals involved with labeling:** Nicola Walters; Angie Giella; Burke Byrne; Marcello Viscomi; Charlene Salmorin; Terri Nataline; Joann Stavole; and Pamela Matheny.

- **Primary Medical Directors/individuals involved with medical affairs:** Jeannette Barrett; Ivan Shaw; Madlen Michael; Gary Kozloski; Jasmine Shah; and Terri Nataline.

- **Primary individuals involved with Kadian® FDA Risk Management Plans:** Joann Stavole and Terri Nataline.

- **Primary individuals involved with FDA submissions and communications generally:** Joyce DelGaudio; Terri Nataline; Joann Stavole; Charlene Salmorin; Burke Byrne; Wendy DeSpain; Sarita Thapar; and Nicola Walters.

TOPIC NO. 20: The studies, Scientific Research, tests, patents, patent applications, trials, or analysis of the safety and efficacy or each Opioid Product, including all such information regarding:

(a) the long-term efficacy of Opioids or use of Your Opioid Products for the treatment of chronic pain or long-term use (more than 90 days);

(b) continual release mechanisms or delivery systems;

(c) the ability of patients to stop using Opioids or Your Opioid Products;

(d) the development of dependence, tolerance, abuse, pseudoaddiction, addiction, or incidence of overdose;

(e) the abuse-deterrent properties of Your or other manufacturers' Opioid Products;

(f) risk of addiction from chronic Opioid therapy;

(g) Opioid withdrawal;

(h) whether Opioid doses can be increased without limit or greater risks;

(i) long-term opioid use and function; and

(j) alternative forms of pain relief posing greater risks than opioids.

JULY 11, 2018 RESPONSE TO TOPIC NO. 20: Allergan Finance incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. Allergan Finance further objects to this Request as overly broad and unduly burdensome, in that it purports to call for detailed testimony regarding "studies, Scientific Research, tests, patents, patent applications, trials, or analysis" as well as "all such information regarding" 10 discrete Topics. Finally, Allergan Finance objects that this Request calls for expert testimony regarding scientific studies related to Opioids. Allergan Finance does not agree to provide testimony regarding this Topic.

AUGUST 24, 2018 AMENDED RESPONSE TO TOPIC NO. 20: Allergan incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. Allergan further objects to this Request as overly broad and unduly burdensome, in that it purports to call for detailed testimony regarding "studies, Scientific Research, tests, patents, patent applications, trials, or analysis" as well as "all such information regarding" 10 discrete Topics. Finally, Allergan objects that this Request calls for expert testimony regarding scientific studies related to Opioids.

Subject to and without waiving its objections, Allergan agrees to provide a written response identifying studies, scientific research and other such analyses regarding Kadian® and Norco®, including those involving subtopics (a) through (j), to the extent they exist and are reasonably available.

JANUARY 15, 2019 WRITTEN RESPONSE TO TOPIC NO. 20: Allergan Finance provides the following information regarding studies, scientific research and other such analyses

regarding Kadian®, Norco®, and Schedule II generic opioids sold by entities previously affiliated with Allergan Finance that have been transferred to Teva Pharmaceutical Industries Ltd.

By providing information regarding generic opioids, Allergan Finance does ***not*** agree that it has any liability (to the extent there is any) for these generic medications. In fact, neither Allergan Finance nor any current affiliate has any such liability or responsibility, and Plaintiffs have not anywhere provided any explanation or factual support for why they might have such liability or responsibility.

Kadian®: Kadian® was approved by the FDA under a New Drug Application ("NDA") in 1996. The NDA was sponsored not by Allergan Finance or any current or former affiliate but rather by another, unaffiliated entity: Faulding Inc. *See generally* ALLERGAN_MDL_00760226. Actavis Elizabeth, LLC (then an affiliate of Allergan Finance) did not acquire Kadian® until December 2008, at which point Kadian® had been prescribed by health care providers, used by patients and regulated by the FDA for more than a decade.

The following are among the studies, scientific research and other such analyses regarding Kadian® prior to its acquisition by Actavis Elizabeth, LLC:

- NDA Study CDD-14556: "[A] randomized, double-blind, double-dummy parallel group study of the relative efficacy and safety of [Kadian®] and MS Contin in the management of moderate to severe cancer pain during a 7-day treatment period." *See, e.g.*, ALLERGAN_MDL_00760226 at -490.
- NDA Study MOR-9/92: "[A] randomized, double-blind, double-dummy, two-period crossover comparison of [Kadian®] capsules q24h with MS Contin® tablets q12h in patients with moderate to severe cancer pain." *See, e.g.*, ALLERGAN_MDL_00760226 at -493.
- NDA Study MOBES-8/90: "[A] randomized, double-blind, double-dummy crossover study comparing the efficacy and safety of [Kadian®] q12h to IRM solution q4h in the management of patients with moderate to severe cancer pain during the two 7 ± 1 day treatment arms of the crossover period. The crossover period was followed by a 12-week open-label assessment of the safety of [Kadian®] q12h." *See, e.g.*, ALLERGAN_MDL_00760226 at -503.

- NDA Study MOR-2/92: Study terminated before completion by Kadian® NDA sponsor Faulding Inc. (an unaffiliated company) due to lack of adequate controls; "no conclusions related to the study efficacy objectives could be drawn," but "[a]ll safety data" reported to the FDA. *See, e.g.*, ALLERGAN_MDL_00760226 at -511.

- NDA Study MOB-1/90: "[A] randomized, open-label, three-way crossover trial comparing the steady-state pharmacokinetics of oral IRM solution q4h, [Kadian®] capsules q12h, and MST Continus® q12h." *See, e.g.*, ALLERGAN_MDL_00760226 at -512.

- NDA Study MOS-1/91: "[A] single-center, open-label, 12-week efficacy and safety evaluation which followed the open-label, randomized pharmacokinetic crossover study MOB-1/90 described above." *See, e.g.*, ALLERGAN_MDL_00760226 at -515.

- NDA Studies MOS-2/91 and MOS-3/91: "These studies entered 29 patients into 9-month open-label extension studies of [Kadian®] q12h in patients with chronic cancer pain who had previously participated in one of the earlier [] studies (Studies MOB-1/90, MOS-1/91 or MOBES-8/90[])." *See, e.g.*, ALLERGAN_MDL_00760226 at -519.

- NDA Study MOR-3/92: "Seven of the eight patients who completed the 9-month studies, MOS-2/91 and MOS-3/91, went on to enroll in the present study which was 12 months in duration." *See, e.g.*, ALLERGAN_MDL_00760226 at -522.

- NDA Study MOR-5/92: "[A] multicenter, open-label, parallel group study to investigate pain control during transfer from IRM solution or MS Contin® tablets to [Kadian®] capsules and from [Kadian®] capsules to parenteral morphine in patients with moderate to severe cancer pain." S*ee, e.g.*, ALLERGAN_MDL_00760226 at -525.

- Jones *et al.*, *Kapanol Capsules: Pellet Formulation Provides Alternative Methods of Sustained-Release Morphine Sulfate*, Clin. Drug Investig., 12(2): 88-93 (August 1996): "Novel methods of administration of morphine for the alleviation of pain in terminally ill patients with cancer who are unable to swallow tablets or capsules or eat or drink have been investigated in in vitro studies. The drug-release rate of Kapanol, a pelletised sustained-release morphine sulfate capsule, was not altered when the pellets were poured onto foodstuffs (including jam, yoghurt, apple sauce and ice-cream) and liquids (orange juice, milk and water). In addition, the drug-release profile of Kapanol pellets was not altered when pellets were flushed with water through a 16 French gastrostomy tube. However, the pellets were too large to pass through a 12 French nasogastric tube. Although clinical studies are needed to determine patient acceptance, these data suggest that sprinkling Kapanol™ pellets onto soft food or liquids or through a gastrostomy tube may be recommended as an alternative method of administration of morphine sulfate."

- Alan Broomhead *et al.*, *Comparison of a Once-a-Day Sustained-Release Morphine Formulation with Standard Oral Morphine Treatment for Cancer Pain*, Journal of Pain and Symptom Management (1997): "This double-blind study compared the efficacy and safety of [Kadian®] every 24 hr to [Kadian®] every 12 hr and MS Contin® tablets (MSC) every 12 hr." *See* ALLERGAN_MDL_000000220.

- Geoffrey K. Gourlay *et al.*, *Pharmacokinectics and pharmacodynamics of twenty-four-hourly Kapanol compared to twelve-hourly MS Contin in the treatment of severe cancer pain*, Pain 69 (1997) 295-305: "Twenty-four patients with severe pain related to cancer completed a randomized, double-blind, double-dummy, crossover study examining morphine pharmacokinetics and pharmacodynamics when the same 24-h morphine dose was administered using two modified release oral morphine formulations; either one dose of [Kadian®] (a new sustained release polymer coated pellet formulation administered in capsule form, Glaxo Wellcome group of companies) per 24 h, or MS Contin (Purdue Frederick Company, Connecticut, USA) administered at 12-h intervals." *See* ALLERGAN_MDL_00000234.

- T. Flöter, E.M.W. Koch, *et al.*, *Comparison of Two Oral Morphine Formulations for Chronic Severe Pain of Malignant and Nonmalignant Origin Kapanol vs MST*, Clin. Drug Invest. 1997 Sept; 14(3): 183-191: "This multicenter, randomized, open-label, parallel study compared the efficacy and tolerability of 12-hourly [Kadian®] with morphine sulfate controlled-release tablets (MST®). Patients with severe chronic pain (n=165) of various origins (73.5% nonmalignant) were randomized and titrated to adequate analgesia with [Kadian®] or MST®, respectively." *See* ALLERGAN_MDL_01132370.

- Robert O. Kerr and William J. Tester, *A Patient Preference Study Comparing Two Extended-Release Morphine Sulfate Formulations (Once-Daily Kadian® versus Twice-Daily MS Contin®) for Cancer Pain*, Clin. Drug Invest. 2000 Jan; 19(1): 25-32: "A randomized, open-label, multicenter, crossover study was conducted in 178 patients requiring treatment for cancer pain, of which 134 were included in the tolerability analysis and 114 took part in the efficacy analysis." *See* ALLERGAN_MDL_02174317.

- E. Ross, J. Sasaki, A. Weil, B. Nicholson, *Improved quality of life with Kadian® (morphine sulfate sustained-release capsules) in patients with chronic, non-malignant, moderate/severe pain: The KRONUS-MSP trial*, Journal of Pain (April 2004): "Alleviating pain and sleep disturbances while minimizing adverse events are all important treatment goals in patients with chronic non-malignant pain; such 'whole patient' management can improve quality of life (QoL). The KRONUS-MSP trial is the largest study to date to examine the use of a sustained-release opioid for chronic non-malignant pain, and includes measures of QoL. The aim was to assess the improvement in QoL in patients with chronic, non-malignant, moderate to severe pain with Kadian treatment." *See* https://www.jpain.org/article/S1526-5900(04)00314-1/abstract.

- M. Kaplan, A. Miliman, L. Kaplan, M. Collins, *Comparative clinical efficacy and abuse potential of oral long acting opioids in a chronic pain outpatient center*, Journal of Pain (April 2004): "Kadian's low abuse potential is obvious as we never had a reported abuse case in over five years." *See* https://www.jpain.org/article/S1526-5900(04)00314-1/abstract.

- T. Mitchell *et al.*, *Slow-release oral morphine versus methadone: a crossover comparison of patient outcomes and acceptability as maintenance pharmacotherapies for opioid dependence*, Addiction, 99:8: 940-5 (August 2004).

- Julie Chao, *Retrospective Analysis of Kadian® (Morphine Sulfate Sustained-Release Capsules) in Patients with Chronic, Nonmalignant Pain*, Pain Medicine, Vol. 6, No. 3 (2005): "The long-term use of sustained-release morphine for chronic pain was examined by reviewing charts from 68 patients taking Kadian® (morphine sulfate sustained-release capsules; Alpharma U.S. Human Pharmaceuticals Branded Products Division, Piscataway, NJ) from 1998 to 2003 (mean treatment period 12 months). Patients had a wide range of pain conditions, including lower back pain with radiculoneuropathy, neck pain, headache, degenerative disc disease, failed back syndrome, and radiculoneuropathies." *See* ALLERGAN_MDL_01132409.

- M. Royal, *A head-to-head, single-dose trial of KADIAN vs AVINZA 30mg in healthy, opioid-naïve subjects in the fed state: Comparison of pharmacokinetics*, Journal of Pain, Vol. 6, Issue 3, Supplement, S41 (March 2005): "This randomized, double-blind, crossover study compared the pharmacokinetics of morphine and its main metabolites in healthy, opioid, naïve subjects (n=36) and alternates (n=4) who were randomized to receive either KADIAN or AVINZA 30mg after a standard meal." *See* https://jpain.org/article/S1526-5900(05)00176-8/pdf.

- Bruce Nicholson, et al., *Treatment of chronic moderate-to-severe non-malignant pain with polymer-coated extended-release morphine sulfate capsules*, Current Medical Research and Opinion, Vol. 22, No. 3 (2006) 539-550: "The KRONUS-MSP (Kadian®: Response Of Non-malignant, Under-treated Subjects with Moderate/Severe Pain) trial was designed to complement evolving clinical practice by studying whether patients with unsatisfactory control of chronic, non-malignant pain can benefit by being switched to a sustained-release opioid. Accordingly, KRONUS-MSP was a prospective, randomized, open-label, blinded endpoint (PROBE) study using polymer-coated extended-release morphine sulfate capsules (P-ERMS) (KADIAN), an opioid with demonstrated efficacy in cancer pain. . . . The study included more than 200 sites in community settings in the US, and included patients with all non-malignant pain types, regardless of etiology. Along with pain control and tolerability, the study assessed sleep, quality of life, and patient and clinician global assessments of therapy." *See* ALLERGAN_MDL_00759485.

- Bruce Nicholson, et al., *Randomized trial comparing polymer-coated extended-release morphine sulfate to controlled-release oxycodone HCI in moderate to severe nonmalignant pain*, Current Medical Research and Opinion, Vol. 22, No. 8 (2006) 1503-1514: "The purpose of this study was to compare the efficacy, tolerability and safety of [Kadian®] and [OxyContin] in the long-term treatment of chronic, moderate to severe, nonmalignant pain in a community-based population." *See* ALLERGAN_MDL_01878125.

- Franklin Johnson, et al., *Effect of Concomitant Ingestion of Alcohol on the In Vivo Pharmacokinetics of KADIAN (Morphine Sulfate Extended-Release) Capsules*, The Journal of Pain, Vol. 9, No 4 (April), 2008, pp. 330-336: "Because of the high rate of alcohol use in the United States, the potential for drug-alcohol interaction is an important clinical concern. Although it is recommended that alcohol not be used while the patient is taking opioids, results of this in vivo study indicate that the risk of alcohol-induced dose-dumping in connection with the use of KADIAN is negligible."

- Other clinical studies and medical research cited in Kadian® Annual Reports submitted pursuant to 21 C.F.R. § 314.81. *See, e.g.*, ALLERGAN_MDL_02345976.

Kadian®'s FDA-approved Prescribing Information contains additional information about scientific research and information. For example, § 6.1 of the Kadian® Prescribing Information (revised September 2018) contains information regarding "Clinical Trial Experience." *See* https://www.allergan.com/assets/pdf/kadian_pi. The Prescribing Information states, for instance, that "[i]n the randomized study, the most common adverse reactions with KADIAN therapy were drowsiness, constipation, nausea, dizziness, and anxiety" and that "[t]he most common adverse reactions leading to study discontinuation were nausea, constipation (may be severe), vomiting, fatigue, dizziness, pruritus, and somnolence." *Id.* It also contains the following table:

Clinical trial patients with chronic cancer pain (n=227) (AE by Body System as seen in 2% or more of patients)	**Percentage %**
CENTRAL NERVOUS SYSTEM	**28**
Drowsiness	9
Dizziness	6
Anxiety	5
Confusion	4
Dry mouth	3
Tremor	2
GASTROINTESTINAL	**26**
Constipation	9
Nausea	7
Diarrhea	3
Anorexia	3
Abdominal pain	3
Vomiting	2
BODY AS A WHOLE	**16**
Pain	3
Disease progression	3
Chest pain	2
Diaphoresis	2
Fever	2
Asthenia	2
Accidental injury	2
RESPIRATORY	**3**
Dyspnea	3
SKIN & APPENDAGES	**3**
Rash	3
METABOLIC & NUTRITIONAL	**3**
Peripheral edema	3
HEMIC & LYMPHATIC	**4**
Anemia	2
Leukopenia	2

Id.

Further, the Kadian® Prescribing Information (revised September 2018) states that "[i]n clinical trials in patients with chronic cancer pain, the most common adverse events reported by patients at least once during therapy were drowsiness (9%), constipation (9%), nausea (7%), dizziness (6%), and anxiety (6%)" and continues to list "less common side effects expected from

KADIAN or seen in less than 2% of patients in the clinical trials." Similarly, under the heading "Four-Week Open-Label Safety Study," the Prescribing Information states that "[i]n the open-label, 4-week safety study, 1418 patients ages 18 to 85 with chronic, non-malignant pain (e.g., back pain, osteoarthritis, neuropathic pain) were enrolled" and that "[t]he most common adverse events reported at least once during therapy were constipation (12%), nausea (9%), and somnolence (3%)." *Id.*

Norco® and generic opioids: The Federal Food, Drug and Cosmetic Act ("FD&C Act") allows several pathways for the approval of FDA-approved medications. *See, e.g.*, *Determining Whether to Submit an ANDA or a 505(b)(2) Application[:] Guidance for Industry*, FDA Draft Guidance (October 2017), at 2-3 (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579751.pdf) (hereinafter "FDA ANDA Guidance"). In addition to NDAs—like the one for Kadian®—approved under either § 505(b)(1) or § 505(b)(2) of the FD&C Act (*see e.g.*, ALLERGAN_MDL_00760226), applicants may submit Abbreviated New Drug Applications ("ANDAs") to the FDA. *Id.* ANDAs may be submitted under either of two provisions: § 505(j) or § 505(j)(2)(C). *See* FDA ANDA Guidance at 2-3.

Unlike Kadian®, Norco® as well as the generic opioids that were sold by former affiliates of Allergan Finance were approved under ANDAs. ANDA applicants are not required to establish clinical safety and effectiveness before the FDA. To the contrary, "limited confirmatory clinical studies may be acceptable" in the context of an ANDA where the "purpose of those studies is ***not to establish safety and effectiveness***." *See* FDA ANDA Guidance at 7 (emphasis added). ANDAs rely on the FDA's previous determination that the previously approved drug product—*i.e.*, the reference listed drug ("RLD")—is safe and effective.

More specifically, there are two approval pathways for ANDAs. Under the first, § 505(j), ANDAs rely on the FDA's finding that the previously approved drug product—*i.e.*, the reference listed drug ("RLD")—is "safe and effective." *See* FDA ANDA Guidance at 2. ANDAs under § 505(j) "generally must contain information to show that the proposed generic product (1) is the same as the RLD with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) and (2) is bioequivalent to the RLD." *Id.* at 2-3. As most pertinent here, "[a]n ANDA may not be submitted if studies are necessary to establish the safety and effectiveness of the proposed product." *Id.* at 3. The other of the two approval pathways for ANDAs is § 505(j)(2)(C). *Id.* This type of ANDA, known as a "petitioned ANDA," is "for a drug product that differs from the RLD in its dosage form, route of administration, strength, or active ingredient (in a product with more than one active ingredient) and for which FDA has determined, in response to a petition submitted under section 505(j)(2)(C) of the FD&C Act (suitability petition), that studies are ***not*** necessary to establish the safety and effectiveness of the proposed drug product." *Id.* (emphasis added). Put differently, the FDA approves petitioned ANDAs ***unless*** either (i) "investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug" ***or*** (ii) "any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application." *See* 21 U.S.C.A. § 355(j)(2)(C).

Thus, with respect to both Norco® and the generic opioids, the FDA required not independent studies, scientific analyses or research regarding the safety and efficacy of these medications but rather, depending on which of the two approval pathways under which the medications were approved, different showings. *See, e.g.*, FDA ANDA Guidance at 4 ("An ANDA relies on the

[FDA's] finding of safety and effectiveness for an RLD and, as a result, that ANDA may be approved without submission of the same type and extent of information as is required for an NDA to establish the safety and efficacy of the proposed product."). Instead, the FDA relied on its prior findings of safety and efficacy for the applicable RLDs. *E.g.*, *id.*

Please refer to Allergan Finance's Response to Topic 41 for additional information regarding the FDA's determinations regarding the safety and efficacy of Norco® in reliance on the reference listed drug, Vicodin. *See infra* Response to Topic 41; *see also generally* ALLERGAN_MDL_04161181; ALLERGAN_MDL_04161107.

FDA's Opioid Post-Marketing Requirements: As stated in a September 2013 letter from the FDA to Watson Laboratories, Inc. (then an affiliate of an Allergan Finance predecessor), the FDA was "requiring ER/LA opioid analgesic drug sponsors to conduct post-marketing studies and a clinical trial to assess" the "risks of misuse, abuse, hyperalgesia, addiction, overdose, and death associated with the long-term use of ER/LA opioid analgesics." *See* ALLERGAN_MDL_01291325 at -326. Specifically, the FDA announced that it was requiring five post-marketing studies and one clinical trial. *Id.* The FDA required these Post-Marketing Requirements ("PMRs") pursuant to its authority under section 505(o) of the FD&C Act. *See* 21 U.S.C. 355(o); *Postmarketing Studies and Clinical Trials — Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act*, FDA Guidance for Industry (April 2011) (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf) (hereinafter "FDA PMR Guidance"). Section 505(o) was by the Food and Drug Administration Amendments Act of 2007. *Id.* at 1. More specifically, Section 505(o)(3) gives the FDA the authority to "require certain postmarketing studies and clinical trials" for prescription drugs. *Id.*

Watson Laboratories, Inc. was included in these PMRs as the sponsor of Kadian®'s NDA. But, in conducting the PMRs, the FDA encouraged opioid sponsors to "work together with the holders of other approved NDA applications for ER/LA opioid analgesics on these studies and clinical trial to provide the best information possible." *See* ALLERGAN_MDL_01291325 at -329. Accordingly, Allergan and other applicant holders of extended-release/long-acting ("ER/LA") opioids formed the Opioid PMR Consortium ("OPC"). Other participants in the OPC are BDSI (Belbuca), Collegium Pharmaceutical (Xtampza ER), Daiichi Sankyo, Inc. (MorphaBond ER), Depomed Inc (Nucynta ER), Egalet (Arymo ER), Endo Pharmaceuticals Inc. (Opana ER), Janssen Pharmaceuticals Inc (Duragesic), Pernix Ireland Pain Designated Activity Company (Zohydro ER), Pfizer Inc. (Embeda and Troxyca ER), Purdue Pharma LP (OxyContin, MS Contin, Butrans, Targiniq ER, and Hysingla ER,), SpecGX LLC (Exalgo), and West-Ward Corp (Dolophine). *See* ALLERGAN_MDL_02207937 at -7941 to -7942.

In February 2016, according to a letter from the FDA to former Allergan Finance affiliate Actavis Laboratories UT, Inc., the FDA replaced the original five post-marketing studies and one clinical trial with ten post-marketing studies and one clinical trial. *See* ALLERGAN_MDL_02023773 at -775 to -779. The eleven opioid PMRs are the following (*see, e.g.*, ALLERGAN_MDL_02207937 at -7947 to -7949):

- PMR 3033-1: "A prospective, observational study designed to quantify the serious risks of misuse, abuse, and addiction associated with long-term use of opioid analgesics for management of chronic pain among patients prescribed ER/LA opioid analgesics."
- PMR 3033-2: "An observational study designed to measure the incidence and predictors of opioid overdose and death (OOD), as well as opioid abuse/addiction, using patient health records, insurance claims, and death records."
- PMR 3033-3: "A prospective observational study designed to assess the content validity and patient interpretation of the Prescription Opioid Misuse and Abuse Questionnaire (POMAQ). Patient understanding of the concepts of misuse and abuse will also be obtained."

- PMR 3033-4: "An observational study to evaluate the validity and reproducibility of the Prescription Opioid Misuse and Abuse Questionnaire (POMAQ), which will be used to identify opioid abuse and misuse behaviors among participants who have chronic pain which requires long-term opioid analgesic use."

- PMR 3033-5: "An observational study to validate measures of prescription opioid Substance Use Disorder and addiction in patients who have received or are receiving opioid analgesics for chronic pain."

- PMR 3033-6: "An observational study to develop and validate an algorithm using coded medical terminologies and other electronic healthcare data to identify opioid-related overdose and death."

- PMR 3033-7: "An observational study to develop and validate an algorithm using coded medical terminologies to identify patients experiencing prescription opioid abuse or addiction, among patients receiving an ER/LA opioid analgesic."

- PMR 3033-8: "An observational study using coded medical terminologies and other electronic healthcare data to define and validate doctor and/or pharmacy shopping outcomes by examining their association with abuse and/or addiction."

- PMR 3033-9: "An observational study using a validated patient survey to evaluate the association between doctor/pharmacy shopping outcomes and self-reported misuse and abuse."

- PMR 3033-10: "An observational study using medical record review to evaluate the association between doctor/pharmacy shopping outcomes and patient behaviors suggestive of misuse, abuse and/or addiction."

- PMR 3033-11: "Conduct a clinical trial to estimate the serious risk for the development of hyperalgesia following the long-term use of high-dose ER/LA opioid analgesics for at least one year to treat chronic pain. Include an assessment of risk relative to efficacy."

The FDA requires applicants to periodically report on the status of PMRs. *See* FDA PMR Guidance at 12-13. The OPC issued an annual report for the period of January 1, 2017 to December 31, 2017. *See generally* ALLERGAN_MDL_02207937. The OPC's 2017 annual report contains information regarding the status of each of the PMRs listed above. *See, e.g.*, *id.* at -7946 to -7949.

TOPIC NO. 28: Your knowledge regarding abuse, misuse, dependence, or addiction potential for Your Opioid Products, including, but not limited to, reports of death, overdoses, abuse, or misuse of Your Opioid Products prior to Allergan's purchase of Kadian®.

JULY 11, 2018 RESPONSE TO TOPIC NO. 28: Allergan Finance incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. Allergan Finance also objects to this Request as vague, ambiguous, overly broad and unduly burdensome to the extent it purports to call for all "knowledge" regarding several broad subject areas.

Subject to and without waiving its objections, Allergan Finance agrees to meet and confer with Plaintiffs regarding the scope and types of information Plaintiffs are requesting.

AUGUST 24, 2018 AMENDED RESPONSE TO TOPIC NO. 28: Allergan incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. Allergan also objects to this Request as vague, ambiguous, overly broad and unduly burdensome to the extent it purports to call for all "knowledge" regarding several broad subject areas.

Subject to and without waiving its objections, Allergan agrees to provide a written response identifying RiskMap reports in its possession related to Kadian® and Norco®, if any, to the extent reasonably available.

JANUARY 15, 2019 WRITTEN RESPONSE TO TOPIC NO. 28: Subject to and without waiving its objections, Allergan states that RiskMap reports regarding its Opioid Products can be found at the following Bates numbers: Kadian® (ALLERGAN_MDL_00640824, ALLERGAN_MDL_00822056, ALLERGAN_MDL_00829076, ALLERGAN_MDL_01287898), buprenorphine hydrochloride and buprenorphine hydrochloride/naloxone (ALLERGAN_MDL_00344529), oxymorphone (ALLERGAN_MDL_00643179), and oxycodone (ALLERGAN_MDL_01095231). In addition, nationwide adverse events reported related to Kadian® and Norco® can be found at ALLERGAN_MDL_0287002, ALLERGAN_MDL_0287098, NAVIPPRO reports containing adverse event information for Kadian® can be found at ALLERGAN_MDL_01434630, ALLERGAN_MDL_01867547, ALLERGAN_MDL_01867449,

ALLERGAN_MDL_01867687, ALLERGAN_MDL_01434955, ALLERGAN_MDL_01800664, ALLERGAN_MDL_01435362, ALLERGAN_MDL_01435961, ALLERGAN_MDL_01435848, ALLERGAN_MDL_01781561, ALLERGAN_MDL_01236684, ALLERGAN_MDL_01772860, ALLERGAN_MDL_01432552, ALLERGAN_MDL_01778437, ALLERGAN_MDL_01778554, ALLERGAN_MDL_01778672, ALLERGAN_MDL_00641056, ALLERGAN_MDL_00828822, ALLERGAN_MDL_00514657, ALLERGAN_MDL_00632025, ALLERGAN_MDL_00826993, ALLERGAN_MDL_01782101, ALLERGAN_MDL_00821293, ALLERGAN_MDL_00819174, ALLERGAN_MDL_00794735 and ALLERGAN_MDL_00816242, and Kadian® periodic safety reports can be found at ALLERGAN_MDL_01872910, ALLERGAN_MDL_02882460, ALLERGAN_MDL_01807275, ALLERGAN_MDL_01442012, ALLERGAN_MDL_02203239, ALLERGAN_MDL_02202279, ALLERGAN_MDL_02199853, ALLERGAN_MDL_02262299.

TOPIC NO. 41: The identity of any and all information (including scientific data) supporting any statements You made to the FDA, medical professionals, patients, or the public concerning any of the following with respect to any Opioid Product (including Opioids as a class):

(k) Addictiveness;

(l) Propensity for abuse;

(m) Efficacy;

(n) Safety for use longer than 90 days;

(o) Comparisons to non-Opioid analgesics;

(p) Standards of care;

(q) Screening of patients; and

(r) Monitoring of patients.

JULY 11, 2018 RESPONSE TO TOPIC NO. 41: Allergan Finance incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. In

addition, Allergan Finance objects to this Topic as overly broad and unduly burdensome to the extent it purports to call for "[t]he identity of and all information (including scientific data) supporting any statements" made to a number of discrete individuals and entities regarding a number of discrete subject matters over a nearly 20-year time period. Also, Allergan Finance objects to this Topic as vague and ambiguous to the extent it fails to identify the "statements" to which it is referring. Allergan Finance does not agree to provide testimony regarding this Topic.

AUGUST 24, 2018 AMENDED RESPONSE TO TOPIC NO. 41: Allergan incorporates by reference the General Objections, Objections to Instructions and Objections to Definitions. In addition, Allergan objects to this Topic as overly broad and unduly burdensome to the extent it purports to call for "[t]he identity of and all information (including scientific data) supporting any statements" made to a number of discrete individuals and entities regarding a number of discrete subject matters over a nearly 20-year time period. Also, Allergan objects to this Topic as vague and ambiguous to the extent it fails to identify the "statements" to which it is referring.

Subject to and without waiving its objections, Allergan agrees to provide a written response identifying medical and scientific research supporting the NDAs or ANDAs for Kadian® and Norco® as well as the medical and scientific authorities cited in promotional materials for Kadian® and Norco®, to the extent reasonably available.

JANUARY 15, 2019 WRITTEN RESPONSE TO TOPIC NO. 41: Allergan Finance provides the following information regarding medical and scientific research supporting the NDAs or ANDAs for Kadian®, Norco®, and Schedule II generic opioids sold by entities previously affiliated with Allergan Finance that have been transferred to Teva Pharmaceutical Industries Ltd. as well as medical and scientific authorities cited in promotional materials for Kadian®, Norco®, and Schedule II generic opioids sold by the transferred entities.

By providing information regarding generic opioids, Allergan Finance does ***not*** agree that it has any liability (to the extent there is any) for these generic medications. In fact, neither Allergan Finance nor any current affiliate has any such liability or responsibility, and Plaintiffs have not anywhere provided any explanation or factual support for why they might have such liability or responsibility.

The following are the studies contained in the Kadian® New Drug Application ("NDA") dated June 28, 1995 (ALLERGAN_MDL_00760226):

- NDA Study CDD-14556: "[A] randomized, double-blind, double-dummy parallel group study of the relative efficacy and safety of [Kadian®] and MS Contin in the management of moderate to severe cancer pain during a 7-day treatment period." *See, e.g.*, ALLERGAN_MDL_00760226 at -490.

- NDA Study MOR-9/92: "[A] randomized, double-blind, double-dummy, two-period crossover comparison of [Kadian®] capsules q24h with MS Contin® tablets q12h in patients with moderate to severe cancer pain." *See, e.g.*, ALLERGAN_MDL_00760226 at -493.

- NDA Study MOBES-8/90: "[A] randomized, double-blind, double-dummy crossover study comparing the efficacy and safety of [Kadian®] q12h to IRM solution q4h in the management of patients with moderate to severe cancer pain during the two 7 ± 1 day treatment arms of the crossover period. The crossover period was followed by a 12-week open-label assessment of the safety of [Kadian®] q12h." *See, e.g.*, ALLERGAN_MDL_00760226 at -503.

- NDA Study MOR-2/92: Study terminated before completion by Kadian® NDA sponsor Faulding Inc. due to lack of adequate controls; "no conclusions related to the study efficacy objectives could be drawn," but "[a]ll safety data" reported to the FDA. *See, e.g.*, ALLERGAN_MDL_00760226 at -511 to -512.

- NDA Study MOB-1/90: "[A] randomized, open-label, three-way crossover trial comparing the steady-state pharmacokinetics of oral IRM solution q4h, [Kadian®] capsules q12h, and MST Continus® q12h." *See, e.g.*, ALLERGAN_MDL_00760226 at -512.

- NDA Study MOS-1/91: "[A] single-center, open-label, 12-week efficacy and safety evaluation which followed the open-label, randomized pharmacokinetic crossover study MOB-1/90 described above." *See, e.g.*, ALLERGAN_MDL_00760226 at -515.

- NDA Studies MOS-2/91 and MOS-3/91: "These studies entered 29 patients into 9-month open-label extension studies of [Kadian®] q12h in patients with chronic cancer pain who had previously participated in one of the earlier [] studies (Studies MOB-1/90, MOS-1/91 or MOBES-8/90[])." *See, e.g.*, ALLERGAN_MDL_00760226 at -519.

- NDA Study MOR-3/92: "Seven of the eight patients who completed the 9-month studies, MOS-2/91 and MOS-3/91, went on to enroll in the present study which was 12 months in duration." *See, e.g.*, ALLERGAN_MDL_00760226 at -522.

- NDA Study MOR-5/92: "[A] multicenter, open-label, parallel group study to investigate pain control during transfer from IRM solution or MS Contin® tablets to [Kadian®] capsules and from [Kadian®] capsules to parenteral morphine in patients with moderate to severe cancer pain." S*ee, e.g.*, ALLERGAN_MDL_00760226 at -525.

The following are among the medical and scientific authorities cited in promotional materials for Kadian®:

- The FDA-approved Prescribing Information (*e.g.*, ALLERGAN_MDL_00992372; ALLERGAN_MDL_00001236; ALLERGAN_MDL_01126158);

- Smith HS, *Opioid Metabolism* , Mayo. Clin. Proc. (July 2009) (ALLERGAN_MDL_00001236);

- Geoffrey K. Gourlay *et al.*, *Pharmacokinectics and pharmacodynamics of twenty-four-hourly Kapanol compared to twelve-hourly MS Contin in the treatment of severe cancer pain*, Pain 69 (1997) (*e.g.*, ALLERGAN_MDL_01103851; ALLERGAN_MDL_00001236);

- Weil A, Nicholson B, Ross E, Sasaki J, *Patients with chronic, non-malignant, moderate/severe pain can be successfully switched from other sustained-release morphine or oxycodone compounds to Kadian (morphine sulfate sustained-release capsules): the KRONUS-MSP trial* (poster presentation 2004) (*e.g.*, ALLERGAN_MDL_01103851);

- Moskowitz, MA, *Advances in understanding chronic pain*, Neurology 2002; 59:1 (*e.g.*, ALLERGAN_MDL_00438900);

- *Americans Living with Pain: Executive Summary of Results* (April 2004 survey) (*e.g.*, ALLERGAN_MDL_00438900);

- Floter et al., *Comparison of two oral morphine formulations for chronic severe pain of malignant and nonmalignant origin: Kapanol vs MST*, Clin Drug Invest. 1997; 14(3) (*e.g.*, ALLERGAN_MDL_00438900);

- Sasaki J *et al.*, *Kadian (morphine sulfate sustained-release capsules) is effective and safe for elderly patients with crhonic non-malignant, moderate/severe pain: the KRONUS-MSP trial* (poster presentation 2004) (*e.g.*, ALLERGAN_MDL_00438900);

- Ross E *et al.*, *Kadian (morphine sulfate sustained-release capsules) improves quality of life in patients with chronic, non-malignant, moderate/severe pain: efficacy, tolerability, and safety results from the KRONUS-MSP trial* (poster presentation) (*e.g.*, ALLERGAN_MDL_00438900);

- Gordon DB *et al.*, *Opioid equianalgesic calculations*, J. Palliat Med. 1999;2(2) (*e.g.*, ALLERGAN_MDL_00438900);
- Levy M.H., *Pharmacologic treatment of cancer pain*, N. Engl. J. Med. 1996;335(15) (*e.g.*, ALLERGAN_MDL_00438900);
- Baumann TJ, *Pain management*, in DiPiro JT *et al.*, *Pharmacotherapy: A pathophysiologic Approach* (1997) (*e.g.*, ALLERGAN_MDL_00438900);
- Smith AP *et al.*, *Opioid analgesics and antagonists*, in Munson PL *et al.*, *Principles of Pharmacology: Basic Concepts & Clinical Applications* (1995) (*e.g.*, ALLERGAN_MDL_00438900);
- McCaffery M. *et al, Pain: Clinical Manual 2nd ed.* (1999) (*e.g.*, ALLERGAN_MDL_00438900);
- American Pain Society, *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain* (5th ed. 2003) (*e.g.*, ALLERGAN_MDL_00438900);
- Twycross RG *et al.*, *Textbook of Pain* (1994) (*e.g.*, ALLERGAN_MDL_00438900);
- Hanks G. *et al.*, *Opioid analgesic therapy*, in Doyle D. *et al.*, *Oxford Textbok of Palliative Medicine* (2d ed. 1998) (*e.g.*, ALLERGAN_MDL_00438900);
- Miyoshi HR *et al.*, *Systemic opioid analgesics*, in Loeser JD *et al.*, *Bonica's Management of Pain* (3d ed. 2001) (*e.g.*, ALLERGAN_MDL_00438900);
- Bonica J.J. *et al.*, *Cancer pain.*, in Bonica J.J, ed., *The Management of Pain* (2d ed. 1990) (*e.g.*, ALLERGAN_MDL_00438900);
- Supernaw R.B., *Pharmacotherapeutic management of selected pain phenomena*, in Weiner R.S., ed., *Pain Management: A Practical Guide for Clinicians* (1998) (*e.g.*, ALLERGAN_MDL_00438900);
- Mandema J.W. *et al.*, *Characterization and validation of a pharmacokinetic model for controlled-release oxycodone*, Br. J. Clin. Pharmacol. (1996) (*e.g.*, ALLERGAN_MDL_00438900);
- FDA-approved Prescribing Information of other medications (*e.g.*, ALLERGAN_MDL_01103851);
- Labby D. *et al.*, *Opioids and Chronic Non-malignant Pain: A Clinician's Handbook* (*e.g.*, ALLERGAN_MDL_01287834);
- Red River Valley Group, *Myths about Morphine* (*e.g.*, ALLERGAN_MDL_01287834);

- American Pain Society, *Guidelines for the Management of Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis* (2002) (*e.g.*, ALLERGAN_MDL_01287834);
- Royal M., *A prospective, randomized, double-blind, crossover, head-to-head, single-dose trial of KADIAN vs. AVINZA 30 mg in 36 opioid-naïve subjects in the fed state* (poster presentation 2004) (*e.g.*, ALLERGAN_MDL_01287834);
- Nicholson B. *et al.*, *Treatment of chronic moderate-to-severe non-malignant pain with polymer-coated extended-release morphine sulfate capsules*, Curr. Med. Res. Opin. (2006) (*e.g.*, ALLERGAN_MDL_01287834).

Norco® is sold under two Abbreviated New Drug Applications ("ANDAs"), application numbers 040099 and 040148. As explained above, ANDA applicants are not required to independently establish clinical safety and effectiveness for FDA approval. *See supra*, Response to Topic 20. Instead, ANDA applicants rely on the FDA's previous determination that the referenced listed drug is safe and effective. *Id.*

One of Norco®'s ANDAs—application number 040148—was originally approved on February 14, 1997. It was originally submitted to the FDA by Watson Laboratories, Inc. (then an affiliate of Allergan Finance predecessor on Watson Pharmaceuticals, Inc.) on June 7, 1995. *See* ALLERGAN_MDL_03276818 at -6818. The FDA's approval package for this ANDA states that the FDA had "concluded that these drugs [referring to, *inter alia*, the 10 mg/325 mg strength of Norco®] are safe and effective for use as recommended in the submitted labeling." *See* ALLERGAN_MDL_04161107 at -1110. Further, the FDA stated: "The drug product, Hydrocodone Bitartrate and Acetaminophen Tablets USP, 10 mg/325 mg (Norco) can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness." *Id.*

The second of Norco®'s ANDAs—application number 040099—was originally approved on June 25, 1997. *See* ALLERGAN_MDL_03280913. This ANDA was submitted not by Allergan Finance or any current or former affiliate but rather by an unaffiliated company, UCB Pharma, Inc.

Id. Watson acquired this ANDA several years later, in or around 2000. *See* ALLERGAN_MDL_03365064 at -5069 to -5070. Prior to the acquisition of this ANDA by Watson, UCB marketed the medication approved under it under the trade name Lortab. *See, e.g.*, https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/040099_S.PDF. Subsequent to the acquisition, Watson (and now an affiliate of Allergan Finance) has sold medications under this ANDA under the trade name Norco®. In approving this ANDA, the FDA stated that it had "completed the review of this abbreviated application" and had "concluded that the drug is safe and effective for use as recommended in the submitted labeling" as well as that the medication could "be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness." *See* ALLERGAN_MDL_04161181 at -1184.

With respect to both ANDAs, the reference listed drug on which the applicants based their submissions and on which the FDA relied for its safety and efficacy conclusions was Vicodin. *See generally* ALLERGAN_MDL_04161181; ALLERGAN_MDL_04161107. By then—1997—Vicodin had been on the market for well over a decade. As Plaintiffs stated in their Complaints, Vicodin (and thus Norco®) has "relatively low opioid content." *See, e.g.*, City of Cleveland Second Amended Compl. at ¶ 105.

Based on its investigation to date, Allergan Finance states that neither it nor any affiliate has detailed Norco® since at least approximately 2003. Among the medical and scientific authorities cited in promotional materials for Kadian® was the FDA-approved Prescribing Information. *See, e.g.*, ALLERGAN_MDL_03255615 *et seq.*

Similar to Norco®, the Schedule II generic opioids were also approved by the FDA under ANDAs, and therefore clinical safety and effectiveness studies were not required for FDA approval. *See supra*, Response to Topic 20. Based on its investigation to date, Allergan Finance has not

identified promotional materials for Schedule II generic opioids that cited medical and scientific authorities. Nor has Allergan Finance identified to date promotional materials for Schedule II generic opioids that made statements or claims specific to those generics such that citation to medical or scientific authorities would be appropriate. Rather, to the limited extent that Allergan Finance's then-affiliates promoted Schedule II generic opioids, the promotion focused on communications relating to the availability of those medications as well as their equivalence to the branded versions. *See, e.g.*, ALLERGAN_MDL_00478888 ("Now Available . . . Authorized Generic of Kadian® (morphine sulfate extended-release) Capsules CII from Actavis."); *see also* ALLERGAN_MDL_00401500 at -1513 (Training materials: "*In your interactions with physicians limit conversations regarding the indication of the product or defer to medical affairs as this is not intended to be a risk/benefit discussion. This is merely an availability announcement.*").

Date: January 15, 2019

Respectfully submitted,

/s/ *Timothy W. Knapp*

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CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2019, the foregoing was sent by electronic mail to counsel for the Plaintiffs and Defendants as follows:

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